

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Morris Samelson and

Johnathan M. Scharff

Serial No.: 10

10/601,796

Filed:

June 23, 2003

For:

Ultra Fine Dead Sea Mineral Compound and Method of Manufacture

Group No.:

1615

Examiner:

Lakshmi Sarada Channavajjala

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop: RESPONSE/FEE Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, on August 23, 2007.

MORKIT SAMELSON

(Printed or typed name of person signing the certificate)

(Signature of the person signing the certificate)

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)

- 1. This declaration is to establish completion of the invention of the above referenced United States Patent application ("Application") in the United States at a date before May 7, 2001, the earliest priority date of prior art application serial US 2003/0211062 ("Laden") that was cited by the Examiner.
 - 2. The person making this declaration is the inventor.

Facts and documentary evidence

- 3. To establish a date of conception of the invention of this application before the priority date of Laden, the following attached documents are submitted as evidence, all of which are true copies of the originals:
 - (i) Manufacturing Batch Record Compounding Module dated February 2, 2001.
 - (ii) Manufacturing Batch Record Milling Module dated February 1, 2001.
 - (iii) Photos of the finished product PharmaSea® Dead Sea Mineral Scrub showing front and back silk screened labeling as well as product lot number stamped into tube corresponding to date of manufacture.
 - (iv) Drawings summarizing invention dated December 2006.
- 4. Laden is a national stage entry of application No. PCT/US01/14570 which was filed on May 7, 2001 and claims priority to an earlier filed provisional application 60/202,409 which fails to disclose the present invention found in Application. Laden was published on November 13, 2003. Laden teaches anhydrous skin cleansers with abrasive materials. The divisional Application was filed on June 23, 2003 and claims priority to filing date August 16, 2001 less than four months after Laden's earliest priority filing date of May 7, 2001.
 - 5. The Applicant avers the following:
 - (a) Applicant conceived the invention before February 2, 2001;
- (b) For a period of approximately one year prior to August of 2000 we had experimented extensively with selected natural ingredients and attempted to include the native Dead Sea minerals but were unable to find a suitable formulation due to the larger granules sizes. Extensive research and development utilizing processed ultra fine Dead Sea minerals (salts) was carried out during the six months prior to January of 2001 in order to develop the processor necessary to process native Dead Sea minerals into ultra fine Dead Sea minerals as novel commercially viable raw material ingredients for esthetically acceptable formulations. The

purpose of the final experimentation in January 2001 (for which charts have been previously submitted to file) was to re-evaluate our findings and determine the final formula best suited as our consumer product PharmaSea® Dead Sea Mineral Scrub product which includes our processed ultra fine Dead Sea minerals having granularity 100% less than 1 mm.

- (e) The Application was filed on June 23, 2001 and is a divisional of application 09/931,453 filed on August 16, 2001.
- 6. From these documents and photos, it can be seen that the invention in the Application was reduced to practice by February 2, 2001 which is earlier than the priority date of Laden.
- 7. The foregoing also establishes the diligence of the Applicant, from the time of conception to the time of constructive reduction to practice.
- 8. Information of further relevance was included in and attached to my previous Declaration under 37 C.F.R. § 1.132 dated January 16, 2007 and submitted to file.
- 9. This declaration is submitted in response to an office action in which Examiner relied on Laden as a reference.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Morris Samelson

Date

ALGUST 23,2007

COMPOUNDING MODULE

ISSUED

(Preparation

(Formula Page

(Bulk Compounding

REVIEWED

(r) Preparation

() Formula Page

(J Bulk Compounding

Issued By: Monkis Stongeson Date: 02/02/01

Reviewed By: Johnaflan A. Scharff 707

PharmaSea® Dead Sea Mineral Scrub Module: Compounding Product Name: Date: 02/02/01 Date: 02/12/0/ Approved By: Prepared By:

Earth Salts International Inc. Manufacturing Batch Record

Date of Manufacture: February 2, 2001

	PREPARATION	Performed By:	Verified By:
I. Equipment Required			
a. Primary compounding vessel:Scott Turbon Mixer (triple mcb. Swift Heating Systemc. Swift Chilling System	Primary compounding vessel: Scott Turbon Mixer (triple motion processor), 200 gal. Swift Heating System Swift Chilling System		
II. <u>Preliminary Work</u>			·
a. Batch DOES NOT r System.	Batch DOES NOT require QA release prior to filling. Use Yellow Tank Card System.		
III. Safety Precautions			S
a. Eye protection must be worn	st be worn during entire manufacturing process.	M	<u>ب</u>
THE ABOVE SAFETY PRECAU'S SIGNED AND DATED BELOW:	THE ABOVE SAFETY PRECAUTIONS HAVE BEEN READ, UNDERSTOOD, SIGNED AND DATED BELOW:		
02/02/02	02/02/01		
Prepared By: MS	Module: Page: Of: Section: Page: Of: Compounding 2 8 Preparation 1 1	Document No. C001.001.00	
Approved By: \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Dead Sea Miner	Lot Code: 20201 (corresponds to date)	

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Part Number	Description	%w/w Contr	Control Number	Amount	Amount Weighed	Amount Performed Checked Weighed By:	Checked Bv:
	Salt Phase)		
2001	Processed ULTRA FINE Dead Sea Salts	51.00		816 Lb	018	2 N	Day 1
	Oil Phase						
1001	Palm oil	25.00		400 Lb	001	MS	M
1002	Soybean oil	9.00		144 Lb	767	MS	
1003	Olive oil	5.00		80 Lb	08	MS	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
1004	Jojoba oil	3.00		48 Lb	26	SM	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
1005	Beeswax	3.00		48 Lb	25	MS	M
1006	Jojoba wax PEG 120	1.00		16 Lb	91	INS	
1007	Cashew husk oil ethoxylate (Clarit)	1.00		16 Lb	91	18	> 1
1008	Coconut oil	1.00		16 Lb	9)	M	
1009	Vitamin E oil (Covitol 1250)	1.00		1.6 Lb	9.1	MS	N N
1010	Vitamin E oil (Covi-ox)	0.05		0.8 Lb	8.0	NS N	1
Prepared By:	Module:	Page:	Of:	Section:	Page: Of:	Document No.	
Approved By:	Product Name:	ne:		ıımıa	7	Lot Code: 20201	

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Earth Salt	Earth Salts International Inc. Manufacturing Batch Record	ring Batch	1 Record	Д	ate of Manu	Date of Manufacture: February 2, 2001	uary 2, 2001
Part Number	Description	M/M%	Control Number	Amount	Amount	Performed By:	Checked Bv:
	Fragrance Phase (essential oil blend)					•	
1012	Rosewood Oil	0.44		7.04 Lb	7.84	SM	\\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\
1013	Lavender Oil	0.34		5.44 Lb	× 24	SM	· ·
1014	Chamomile Oil	0.20		3.20 Lb	3.20	145	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
1015	Calendula Oil	0.02		0.32 Lb	6.32	MS	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Prepared By:	MS Module:	Page: ding 4	Of:	Section: Formula	Page: Of:	Document No.	
Approved By:	Product Name: PharmaSea@	ne: :a® Dead S	er	Scrub		Lot Code: 20201 (corresponds to date)	ate)

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Manufacturing Batch Record

Date of Manufacture: February 2, 2001

	BULK COMPOUNDING			Performed By:	Verified By:
I. Oil Phase:	ĭ				
a. Add to the Primary C Turn on heating syste Heat contents to 65°C	Add to the Primary Compounding Vessel when temp reaches 35°C; Turn on heating system and open flow through jacket in vessel. Heat contents to 65°C while mixing slow speed.	reaches 3: t in vessel.	, , ,		
Palm Oil		400 Lb	<u> </u>	SW .	~
Beeswax		48 Lb	5	`	
Jojoba Wax PEG 120		16 Lb	7		
Beeswax		48 Lb	7]		
Cashew Husk Oil Exthoxylate (Clarit)	thoxylate (Clarit)	16 Lb	2		
Prepared By: ME	Module: Page:	Of: Section:	Section: Page: Of: Bulk Commoning 1-4	Document No.	
Approved By: \sqrt{M}	Sead S	Mineral S	Jamana	Lot Code: 20201	

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Manufacturing Batch Record

Date of Manufacture: February 2, 2001

	BULKC	BULK COMPOUNDING-cont'd	-cont'd		Performed By:	Verified By:
	 b. When a. reaches 65°C and is completely melted together increase mixing with high speed agitation and add: 	s completely melte	ed together ir	crease mixing with high	(
				ADDED	MIS	S = = = = = = = = = = = = = = = = = = =
	Soybean oil		144.0 Lb	3 2		
	Olive oil		80.0 Lb	3	nd for an	
	Jojoba oil		48.0 Lb	2 e		
	Covitol 1250		1.6 Lb	CP (2)		
	Covi-ox		0.8 Lb	, d		
	Increase speed of scrape surface agitation and triple impellor to medium. Turn off heating system and close off flow of hot water to jacket of vessel. Turn on Turbon (turbine) for high speed homogeneous mixing/agitation.	e agitation and trip w of hot water to j eneous mixing/agit	ole impellor to jacket of vess tation.	o medium. Turn off sel. Turn on Turbon		
		OILP	OIL PHASE COMPLETED	APLETEDI.		**************************************
Π.	Salts Phase:					
	a. Add ULTRA FINE Dead Sea	a Salts and continue higher speed mixing:	ue higher spe	eed mixing:		
	ULTRA FINE Dead Sea Salts		816.00 Lb) J		`
					SM	^
Prepared By:	" MES	Module: Compounding	Page: Of: 6 8	Section: Page: of: Bulk Compounding 2 4	Document No. C001.001.00	
Approved By:	3y: NAS	Product Name: PharmaSea® Dead Sea Mineral Scrub	ead Sea Mine	eral Scrub	Lot Code: 20201	

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Verified By:		S								S		
Performed By:		MS								MS	Document No. C001.001.00	Lot Code: 20201 (corresponds to date)
BULK COMPOUNDING cont'd	Turn on chiller system and open flow valves for chilled water. Set temperature control on jacketed process vessel to 45°C to open valves. Continue mixing with triple motion until batch temperature reaches 45°C. Continue for 15 minutes at maintained 45°C.	SALTS PHASE II. COMPLETEDII.	III. <u>Fragrance Phase (essential oil blend)</u> Set temperature control to 42°C and add the following once temperature of batch becomes 42°C.	a. Combine the following in a suitable stainless steel container: ADDED	Rosewood oil 7.04 Lb (Lavender oil 5.44 Lb (Chamomile oil 3.20 Lb	Calendula oil 0.32 Lb	FRAGRANCE PHASE COMPLETEDIII.	Maintain batch at 42°C while mixing for 10 minutes. Set temperature control on jacketed process vessel to 40°C. When temperature of batch arrives at 40°C begin pumping from Scott to tube filling machine for filling tubes.	MS	Approved by: M S Product Name: PharmaSea® Dead Sea Mineral Scrub

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	BUILK COMPOUNDING-cont'd	renormed by:	vernieu by:
>	Reconciliation		
	a. Weigh and record: GROSS: lo 50 Lb		
	TARE: 15.62 Lb		
	NET WEIGHT: 1584.38 Lb		
	Net Weight:		
	b. Calculate and record Compounding loss:		
	($ \emptyset00\rangle$ Lb) – (Net Weight: $ 594.34\rangle$ Lb) = Compounding Loss: $ 5.62\rangle$ Lb		
	NOTE: Yield limits are 97-103%. If outside this range, notify supervisor.		
	PHASE IV. COMPLETEDIV.	MS	5
VI.	Sampling		-
	a. Submit two four ounce samples to QA.		
	PHASE V. COMPLETEDV.	MS	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Prepared By:	Module: Page: Of: Section: Page: Of: Compounding 8 8 Bulk Compounding 4 4	Document No. C001.001,00	
Approved By:	Product Name: PharmaSea® Dead Sea Mineral Scrub	Lot Code: 20201 (corresponds to date)	

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(ATMOSULTRAMILL) MILLING MODULE

ISSUED

(Preparation

(Description Pages

(S) Bulk Milling

REVIEWED

(*) Preparation

(v) Description Pages

 (ν) Bulk Milling

Issued By: MORKIS SAMELSAN

Date: 02/01/01

Reviewed By: Johnstoff H. Scharff Date: 02/01/01

Processed ULTRA FINE Dead Sea Minerals (salts) Page: Raw Material Name: Milling Module: Date: 02/01/01) Date: 02 / Approved By: Prepared By:

Manufacturing Batch Record

Date of Manufacture: February 1, 2001

PREPARATION	Performed By:	Verified By:
Equipment Required		
 a. Primary milling system: Modified Conical Screen Mill b. Hapman infeed conveyor (infeed to milling system) c. Hapman outfeed conveyor (for drum fill on weigh scale) d. Dust control system, Metler floor scale, wench 		
Preliminary Work	(
a. Batch DOES NOT require QA release prior to milling.	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	5
Safety Precautions	>	
a. Eye protection must be worn during entire manufacturing process. Dust control system must be attached and activated prior to and during milling process. All electric controls to be checked prior to plug in of systems with all switches in off position.		
THE ABOVE SAFETY PRECAUTIONS HAVE BEEN READ, UNDERSTOOD, SIGNED AND DATED BELOW: WARM OZ/OL/OL OZ/OL/OL OZ/OL/OL		
Module: Page: Of: Section: Page: Of: Milling 2 7 Preparation 1 1	Document No. M001.001.00	
Product Name: Processed ULTRA FINE Dead Sea Minerals (salts)	Lot Code: 20101AUM (Include date)	UM

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Earth Salt	Earth Salts International Inc. Manufactu	Manufacturing Batch Record	D	ite of Man	Date of Manufacture: February 1, 2001	nary 1, 2001
Part Number	Description of processed raw material produced in house	7	Amount needed	Amount Weighed	Performed By:	Checked By:
	PROCESSED RAW MATERIAL					
2001	(Processed) ULTRA FINE Dead Sea Salts		910 Lb	906	SM	5
	Size: 100% less than 1 mm and 10 mesh US Sieve unit.					
	Suitable for use in manufacturing products that require scrubbing effect as well as those that do not require scrubbing effect. (Grade 1) Action: 910 Lb native Dead Sea minerals (salts) processed through proprietary ATMOSULTRAMILL system with modified room atmosphere with temperature 75°F with cool dry positive pressure. RPM 4800. Material Choke fed. Native Dead Sea Salts have been successed in the properties of the page and the page of t	s (salts) processed throughture 75°F with cool dry processed throughture 75°F	th proprietary	ATMOSUL	TRAMILL syst	em with
	attached including Typical Analysis.	Marine Octive Fine D	cau oca oalio	. Ivauve Dea	d Sea Saits infoi	mation
Prepared By:	Module: Milling	Page: Of: 3 7	Section: Description	Page: Of: 1 2	Document No. M001.000.00	
Approved By:	Raw Material Name: Processed ULTR	A FINE Dea	ea Minerals (salts)	Lot Code: 20101AUM	AUM
				7744		

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Earth Salt	Earth Salts International Inc. M	Manufacturing Batch Record		ate of Manu	Date of Manufacture: February 1, 2001	uary 1, 2001	
Part Number	Description of processed raw material produced in house	material	Amount	Amount Weighed	Performed By:	Checked By:	
	PROCESSED RAW MATERIAL	IAL					· · · · · ·
2002	(Processed) ULTRA FINE Dead Sea Salts	d Sea	110 Lb	801	SM	57	.,
	Size: 100% Less than 1 mm and 10 mesh US Sieve unit.	d 10 mesh				,	1
	Suitable for use in manufacturing products that require scrubbing effect as well as those that do not require scrubbing effect. (Grade 2)	effect as					
	110 Lb native Dead Sea minerals (salts) processed through proprietary ATMOSULTRAMILL system with modified room atmosphere with temperature 75°F with cool dry positive pressure. RPM 4800. Change part for finer material. Material choke fed. Native Dead Sea Salts have been processed into ULTRA FINE Dead Sea Salts. Native Dead Sea Salts information attached including Typical Analysis.	ls (salts) processed through pure 75°F with cool dry positid Sea Salts have been procesting Typical Analysis.	proprietary ATMC ive pressure. RPM seed into ULTRA	SULTRAMII 14800. Chang FINE Dead Se	LL system with e part for finer 1 ea Salts. Native	modified material. Dead Sea	
Prepared By:	US	Module: Page: Of:	Section: Description	Page: Of:	Document No.		
Approved By:	SM	Raw Material Name: Processed ULTRA FINE Dead Sea Minerals (salts)	ead Sea Minerals	(salts)	Lot Code: 20101AUM	AUM	
	_						

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Manufacturing Batch Record

Earth Salts International Inc.

Grade 1: Connect Hapman conveyors to mod. conical screen mill with attached dust control and Metler floor scale for weigh activated filling of fiber drums with 4 mil inner liner bags (lock tied) forming ATMOSULTRAMILL: Activate system (turn on all components) and begin adding native Dead Sea Salts to in-feed hopper as needed to maintain steady fill rate on drums. Native Dead Sea Salts	
I. Connect Hapman conveyors to mod. conical screen mill with attached dust control and Metler floor scale for weigh activated filling of fiber drums with 4 mil inner liner bags (lock tied) forming ATMOSULTRAMILL: Activate system (turn on all components) and begin adding native Dead Sea Salts to in-feed hopper as needed to maintain steady fill rate on drums. Native Dead Sea Salts	
	SX.
attached}	
Fill and stack drums in warehouse for utilization in PharmaSea® Dead Sea Mineral Scrub product manufacturing on 02/02/01.	
CLEAN SYSTEM THOROUGHLY	
Orace 2: II. Change parts for finer grade ULTRA FINE and repeat II and utilize existing setup of I with change part for finer flour like material. ADDED	
Native Dead Sea Salts {Typical Analysis - description attached}	
Grade 2 run COMPLETEDII.	
SM	SX
Prepared By: Module: Page: Of: Section: Page: of: Document No.	nt No.
ame: ed ULTRA FINE Dead Sea Minerals (salts)	Lot Code: 20101AUM

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	i circinica Dy.	vernieu by:
III Deconsiliation George 1		
ivection of a control of a cont	······	
a. Weigh and record: GROSS: 4/0 Lb		
TARE: 4 Lb		
NET WEIGHT: 906 Lb		
Net Weight: $900 \text{ Lb } \times 100$ = 910.0 Lb % YIELD		
b. Calculate and record Milling loss:		
($^{9/0}$ Lb) – (Net Weight: $^{9/0}$ Lb) = Milling Loss: 1 Lb		
NOTE: Yield limits are 97-103%. If outside this range, notify supervisor.		\
COMPLETEDIII.	MIS	< \
IV. Sampling		
a. Submit two four ounce samples to QA.	((
COMPLETEDIV.	M S	5
Page: Of: Section: Page: Of:	Document No.	
ead Sea Minerals (salts)	Lot Code: 20101AUM	M

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Manufacturing Batch Record

Date of Manufacture: February 1, 2001

	BULK MILLING-cont'd		Performed By:	Verified By:
>.	Reconciliation: Grade 2			
	a. Weigh and record: GROSS: // O_Lb			
	TARE: -2 Lb			
	NET WEIGHT: 108 Lb			
	Net Weight: $ \partial \mathcal{E} = \partial \mathcal{E} = \partial \mathcal{E} = \partial \mathcal{E} = \partial \mathcal{E} $ % YIELD	Q,		
	c. Calculate and record Milling loss:			
	(Lb) – (Net Weight: Lb) = Milling Loss: Lb			
	NOTE: Yield limits are 97-103%. If outside this range, notify supervisor.		Ļ	
	PHASE IV. COMPLETED	V.	MS	^ <u>~</u>
VI.	Sampling			
	a. Submit two four ounce samples to QA.		(
	PHASE V. COMPLETED	VI.	MIS	SZ-
Prepared By:	Module: Page: Of: Section: Milling 7 7 Bulk Milling	Page: Of:	Document No.	
Approved By:	Product Name: Processed ULTRA FINE Des	1 1	Lot Code: 20101AUM	M

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DEAD SEA WORKS LTD

Polash House * P.O.Box 75 * Beer-Sheva 84100, ijirasi Tel. (972-7) 646 5347 * Fax. (972-7) 628 0533 E-mail:chemerket@dsw.co.ii

Marketing Division Chemical Products



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אגף שיווק למוצרים כימיים

January 2000

DEAD SEA BATH SALTS

Typical Analysis

Components		Formula	Typical	Range
			22.2	210 250
Magnesium	Chloride	$MgCl_2$	33.3	31.0 - 35.0
Potassium	Chloride	KCl	24.3	20.0 - 28.0
Sødium	Chloride	NaCl	5.5	3.0 - 8.0
Calcium	Chloride	CaCl ₂	0.2	0.1 - 0.5
Bromide		Br [*]	0.5	0.3 - 0.6
Sulphates		SO ₄ "	0.15	0.05- 0.2
Insolubles		·	0.03	0 - 0.3
Water of Crystallization			36.4	32.0 - 40.0

Screen Analysis

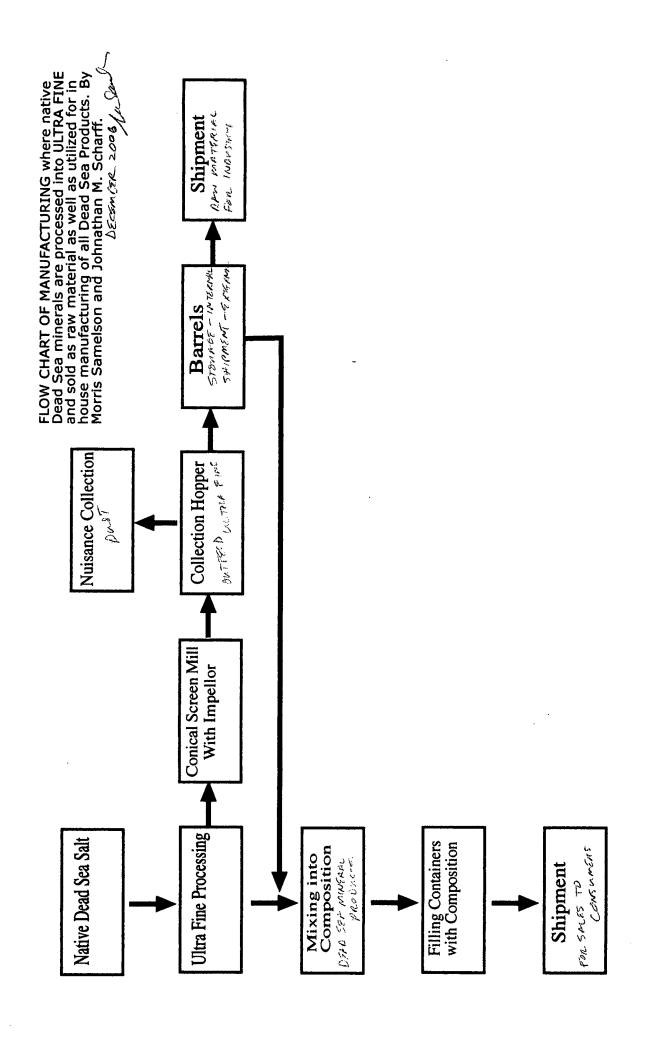
Fine Grade - 90% < 10 mesh 90% < 1.7 mm

Coarse Grade - > 90% between 5 & 10 mesh

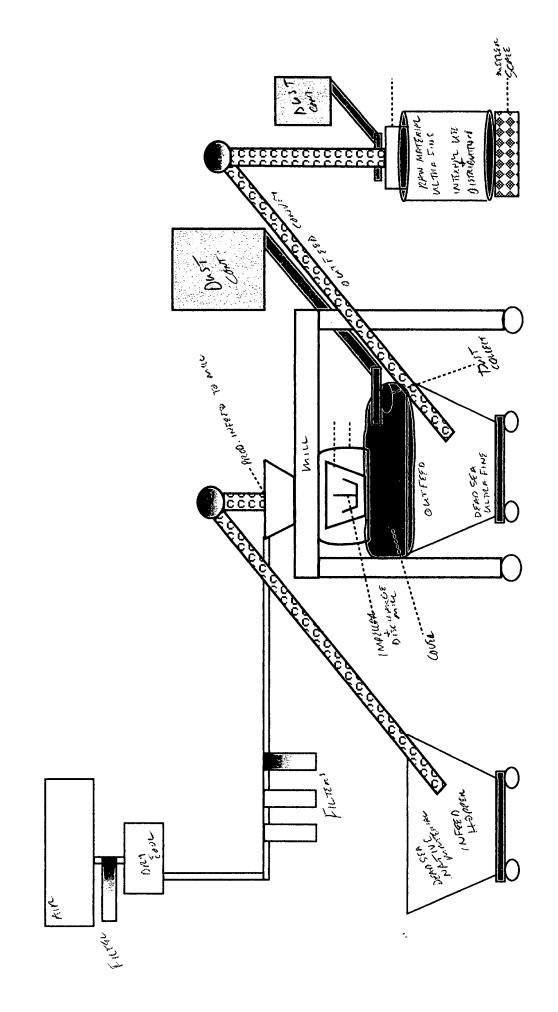
> 90% between 1.7& 4.0 mm

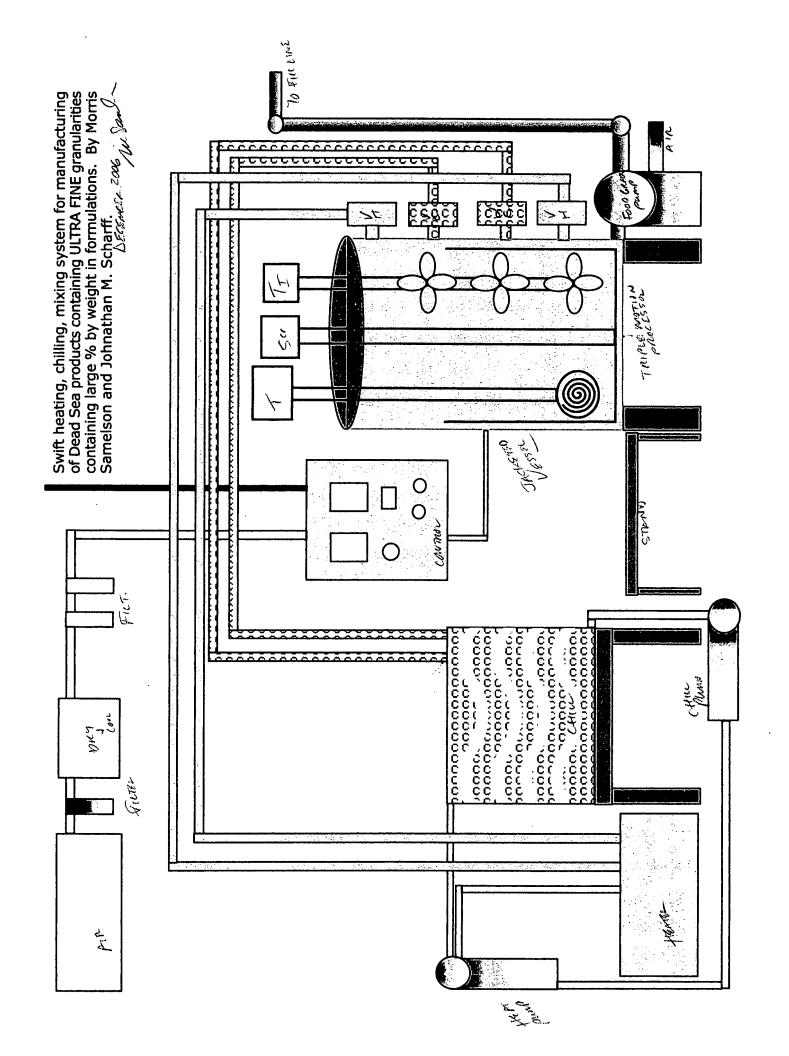
Alan Becker

Chief Process Engineer & Quality Control Manager Chemical Products Division



Milling system for processing Dead Sea Minerals to ULTRA FINE GRANULARITIES less than 1 mm. By Morris Samelson and Johnathan M. Scharff



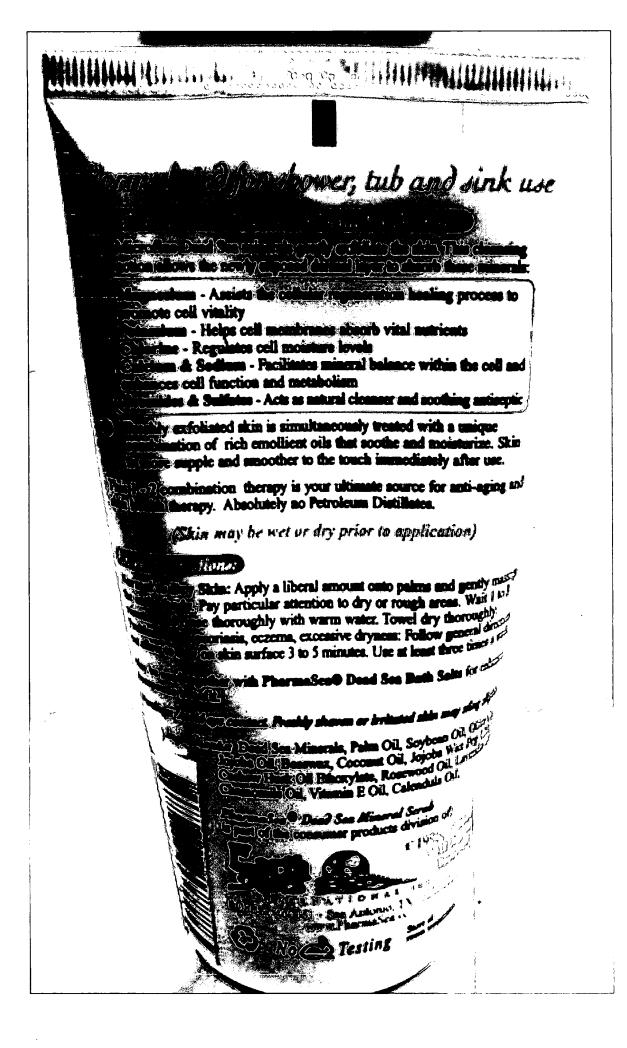


Formulated for shower, tall and sind

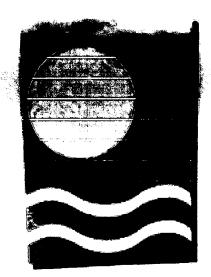
Pharma Sea @ Dead Sea Mineral Serub work

Wicrofine Dead Sea minerals gently existing the dear The taion allows the newly exposed dennal layer to absent

reserven - Assists the cellular regeneration healing senote cell vitality



Scrub



E Pharma Sea°

Life Endancing Minerals Harveste's From Nature's Pharmaty

sea

Advanced Dead Sea Therapy for ultimate skin care es bealth.

100% Natural

Exfoliates

Nourisbes

Rejuvenales

Not Weight = 5 os.

